

**AUG 29 2000**

K002378

## **510(k) Summary of Safety and Effectiveness**

Trade Name: Modular PORP & TORP  
Common Name: Partial Ossicular Replacement Prosthesis  
Total Ossicular Replacement Prosthesis  
Classification Name: Partial Ossicular Replacement Prosthesis (§ 874.3450)  
Total Ossicular Replacement Prosthesis (§ 874.3495)  
Official Contact: Alicia E. Farage  
Senior Regulatory Affairs Specialist  
Smith & Nephew, Inc.  
ENT Division  
2925 Appling Road  
Bartlett, TN 38133  
Telephone: (901) 373-0200  
Fax: (901) 373-0242  
Date Prepared: August 17, 2000

The Modular PORPs and TORPs are substantially equivalent to the HAPEX TORP and PORP marketed by Smith & Nephew, Inc., ENT Division and the Tuebingen Type Bell Vario and Tuebingen Type Aerial Vario marketed by Heinz Kurz GmbH. See the chart below for summarized information in a tabular format.

### Intended Use

The Modular PORP and TORP have the same intended use as the HAPEX PORP and TORP, partial/total reconstruction of the ossicular chain that has lost its function due to disease, trauma, or congenital defect. This is also the same intended use as the Tuebingen Type Bell Vario and Tuebingen Type Aerial Vario.

### Head Material

The Modular Prosthesis differs from the HAPEX PORP and TORP in the material used for the head. The head of Modular PORP and TORP is made from titanium. This material has a long history and wide use in middle ear reconstruction. However, titanium is the same material used in the Tuebingen Type Bell Vario and Tuebingen Type Aerial Vario.

#### Shaft Material

The Modular Prosthesis utilizes the same material as the HAPEX PORP and TORP for the shaft. The shaft is manufactured from HAPEX, a composite material that is trimmable. This composite is 40% hydroxylapatite and 60% high-density polyethylene by volume. The However, titanium is used for the shaft in the Tuebingen Type Bell Vario and Aerial Vario.

#### Design Features

The shafts of the Modular Prostheses are trimmable to allow for intraoperative sizing as are the shafts of the HAPEX PORP and TORP and the Tuebingen Type Bell Vario and Aerial Vario. The heads of the Modular prostheses are flat and circular, as is the Tuebingen Type implant heads. However, the HAPEX implants have oval flattened heads.

	<b>Modular PORP &amp; TORP (Smith &amp; Nephew ENT Division)</b>	<b>HAPEX PORP &amp; TORP (Smith &amp; Nephew ENT Division)</b>	<b>Tuebingen Type Bell Vario and Aerial Vario. (Heinz Kurz GmbH)</b>
<b>Intended Use</b>	Partial/Total Reconstruction of the Ossicular Chain	Partial/Total Reconstruction of the Ossicular Chain	Partial/Total Reconstruction of the Ossicular Chain
<b>Head Material</b>	Titanium	Hydroxylapatite	Titanium
<b>Head Shape</b>	Round	Oval	Round
<b>Shaft Material</b>	HAPEX	HAPEX	Titanium
<b>Intra-operative Sizing</b>	Yes	Yes	Yes
<b>How Supplied</b>	Sterile	Sterile	Yes

Differences between the Titanium Prostheses and the predicate device should not affect the safety or effectiveness.



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

**AUG 29 2000**

Smith & Nephew, Inc.  
Ms. Alicia Farage  
Sr. Regulatory Affairs Specialist  
2925 Appling Road  
Bartlett, TN 38133

Re: K002378  
Trade Name: Partial and Total Ossicular Replacement Prosthesis  
Regulatory Class: II  
Product Code: 77ETA, 77ETB  
Dated: August 02, 2000  
Received: August 04, 2000

Dear Ms. Farage:

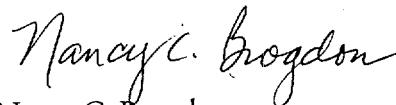
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-6413. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsma/dsmamain.html>".

Sincerely yours,

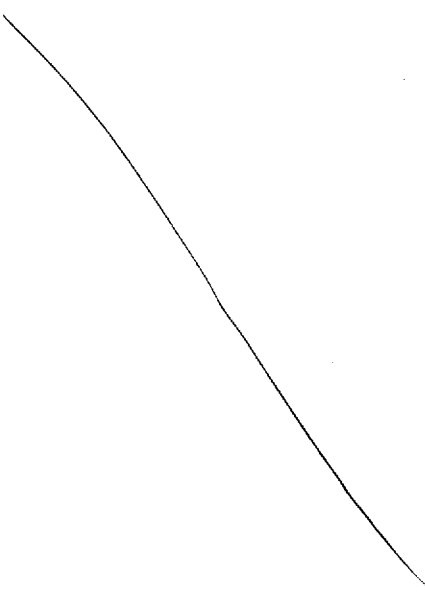
A handwritten signature in cursive script that reads "Nancy C. Brogdon".

Nancy C. Brogdon  
Acting Director  
Division of Ophthalmic and Ear,  
Nose and Throat Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

510(k) Number: K002378  
Device Name: Modular PORP® and TORP®

Indications For Use:

- Otosclerosis
- Congenital fixation of the stapes
- When previous remedial surgery has been unsuccessful for the treatment of hearing loss due to otosclerosis, and a significant conductive loss remains with good cochlear reserve.
- Chronic middle ear disease
- Trauma

  
Karen H. Baker  
(Division Sign-Off)  
Division of Ophthalmic Devices  
510(k) Number K002378

*J. S. Jernan*